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EXAMINER

TOWA, RENE T

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

1. This Office action is responsive to an amendment filed December 29, 2008. Claims 59-77 are pending. Claims 1-58 have been cancelled. Claims 59, 68 & 77 have been amended.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. **Claims 59, 61-66, 68, 70-75 & 77** are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries (US 4,967,762) in view of Markham (US 4,549,554), and further in view of Eldridge (US 4,207,870).

DeVries discloses a high specimen yielding needle aspiration biopsy device, comprising:

a syringe including a barrel 20 and a piston 34 slidable within the barrel 20;
a cup-shaped hub 40 and defining a specimen collection well 62; and
a needle 70 mounted to the hub 40 having a shaft with an open pointed tip;
wherein at least one hub 40 and needle 70 define a passageway 64 extending from the needle tip to inside the hub opening to a floor of the collection well 62 (see DeVries, figs. 1-2).

DeVries disclose a system, as described above, that fails to explicitly teach a valve for controlling an opening in the syringe barrel and an anti-reflux head.

However, **Markham** discloses a syringe 10 including a barrel 12 and a piston 22 slidable with the barrel, the syringe barrel 12 extending along and concentric about a long axis and configured to introduce a vacuum flow;

a valve 28 for controlling transmission of the vacuum flow from the syringe 10 (see figs. 1-2; col. 3, lines 28-37 & 45-55).

Moreover, **Eldridge** discloses a high specimen yield anti-reflux head, comprising:
a cup-shaped hub 10 having a bottom wall surrounded by a sidewalls extending from the bottom wall along a hub 10 axis terminating at a peripheral mouth;

a releasable collar 12 fitting in a liquid tight seal over the peripheral mouth of the hub 10 to define within the hub 10 and collar 12 a specimen collection volume;

an opening in the hub 10 bottom wall receiving a proximal end of a hypodermic needle 14 extending substantially parallel to the hub 10 axis;

a conduit communicating between a lumen of the hypodermic needle 14 received by the opening in the hub 10 bottom wall and an interior opening into the specimen collection volume proximate to one side wall, removed from the bottom wall;

whereby when the axis of the hub 10 is horizontal, the interior opening into the specimen collection may be positioned by an operator in a top position such that sample material from the hypodermic needle 14 entering the specimen collection volume through the interior opening collects against the opposite sidewall in a pool spaced from the interior opening to prevent reflux of the material through the interior opening, and when the axis of the hub 10 is vertical with a distal end of the hypodermic needle 14 extending downward, sample material collects against the bottom wall spaced from the

interior opening to prevent reflux of the material through the interior opening (see figs. 1-4; see abstract; see col. 3, lines 32-41).

In regards to **claims 61 & 70**, Eldridge discloses an anti-reflux head wherein at least the side walls of the hub are transparent (see abstract; see col. 3, lines 32-41).

In regards to **claims 62 & 71**, Eldridge discloses an anti-reflux head wherein the conduit is configured to be visible through the transparent side walls such that an operator can easily identify the top position (see col. 3, lines 32-41).

In regards to **claims 65 & 74**, Eldridge discloses an anti-reflux head wherein the peripheral mouth is capable of receiving a lid to enclose the specimen collection well when the releasable collar 12 is released from the hub 10 (see figs. 1-4).

In regards to **claims 66 & 75**, Eldridge discloses an anti-reflux head wherein the peripheral rim defines a greatest separation of side walls to facilitate access to the specimen collection volume (see figs. 1-4).

In regards to **claims 59, 61-63, 65-66, 68, 70-72, 74-75 & 77**, since DeVries teaches an O-ring and a port 72 that act as a valve to release and create the vacuum in the system (see DeVries, column 1/lines 55-62; column 2/lines 3-12; column 3/lines 1-3 & 8-14), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of DeVries with a stopcock valve as taught by Markham in order to control the flow of fluid to the syringe barrel by releasing and creating the vacuum in the system (see Markham, figs. 1-2).

Moreover, since DeVries teaches that it is known to provide biopsy needle devices with a secondary hub carrying needle with a means for a quick and simple relief

Art Unit: 3736

of the vacuum without dilution of the specimen or contamination thereof (see abstract; see figs. 1-2), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the needle biopsy device of DeVries as modified by Markham with an anti-reflux head as taught by Eldridge in order to quickly and simply relieve the vacuum without dilution of the specimen or contamination thereof.

Furthermore, Eldridge teaches a conduit formed by an open space 28, a passage 26 and open space 30 for allowing fluid to pass in the direction of the annular skirt 22 (see fig. 1; col. 2, lines 60-65), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the needle biopsy device of DeVries as modified by Markham and Eldridge with a conduit that is integrally formed with a sidewall as claimed since such a modification would serve the same purpose of allowing fluid to pass in the direction of the annular skirt. Moreover, it has previously been held that merely making integral is not patentable--*See in re Larson*, 340 F. 2d 965, 967, 144 USPQ 347, 349 (CCPA 1965); *In re Wolfe*, 251 F.2d 854, 855, 116 USPQ 443, 444 (CCPA 1958).

In regards to **claims 64 & 73**, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the needle biopsy device of DeVries as modified by Markham and Eldridge above with a specimen collection volume that is greater than 100 microliters as claimed in order to collect a volume of specimen sufficient for carrying out a biopsy test.

Art Unit: 3736

4. **Claims 67 & 76** are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Markham ('554), Eldridge ('870), and further in view of Guerra (US 3,753,432).

DeVries as modified by Markham and Eldridge disclose an anti-reflux head, that fails to explicitly teach an anticoagulant surface or an interior opening that is directed toward an opposite side wall.

However, **Guerra** teaches a device comprising an anti-coagulant coated surface (see col. 5, lines 1-7); wherein an interior opening is directed toward an opposite side wall (see fig. 1).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the anti-reflux head of DeVries as modified by Markham and Eldridge above with an anticoagulant specimen collection volume as taught by Guerra in order to achieve a device that prevents the collected specimen from drying thereby facilitating testing.

5. **Claims 60 & 69** are rejected under 35 U.S.C. 103(a) as being unpatentable over DeVries ('762) in view of Markham ('554), Eldridge ('870), and further in view of Dann et al. (US 2,840,075)

DeVries as modified by Markham and Eldridge disclose an anti-reflux head, that fails to explicitly teach an interior opening that is directed toward an opposite side wall.

However, **Dann et al.** disclose an apparatus comprising a specimen passageway 30; wherein an interior opening of the specimen passageway 30 is directed toward an opposite side wall (see figs. 4-5).

Since both Eldridge and Dann et al. teach device for visually observing the puncture of the vein, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the anti-reflux head of DeVries as modified by Markham and Eldridge with an interior opening that is directed toward an opposite side wall as taught by Dann et al. in order to more visibly observe the passage of blood into the collection well (see Dann et al., col. 1, line 66 to col. 2, line 13; col. 2, lines 65-68; col. 3, lines 3-9, 14-16 & 33-39).

Response to Arguments

6. Applicant's arguments filed December 29, 2008 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

Art Unit: 3736

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. T./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736